

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of Precoetaneous dilatation tracheotomy usage without fiber optic bronchoscope guidance on the patients candidate for tracheostomy and admitted to the intensive care unit on reduction of postoperative complications

Protocol summary

Summary

Study is done as prospective without blinding on 80 patients with age of at least 18 years candidate for tracheostomy and admitted to the intensive care unit (ICU) at Shahid rajaei hospital during 2106-2017. Patients with great thyroid, undesirable anatomy and Placket disorder are excluded. At first, patient is placed in hyperextension position and intended site is sterile in alcohol with chlorhexidine 2%. The site between the rings 2 and 3 of chips is marked with betadine. With a scalpel, the size of 1.5 cm horizontal incision is created and is pierce with a needle in gauge of fourteen linked to syringe 10 cc content of 2 cc distilled water. The Syringe and needle are exited and Plastic cannula is placed in trachea. Then, guide wire is entered into trachea about 10 cm via plastic cannula and is passed a plastic dilator 14 french over guide wire. Plastic dilator is exited and after entering white dilator and passing rhino dilator to the skin level into trachea and then exiting rhino dilator via metal guide wire, tracheostomy tube in suitable size is placed into trachea. metal guide wire and white dilator are exited and after bilateral symmetry lung sound and confirming tracheostomy tube site into trachea, Orotracheal tube is exited. After one hour, chest x-ray is taken. Rate of Bleeding, loss of oxygen saturation less than 90%, exiting or rupture of trachea tube, incidence of pneumothorax and Subcutaneous emphysema, incorrect embedding tracheostomy tube and related death are assessed in patients to 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061923473N3**

Registration date: **2017-07-06, 1396/04/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-06, 1396/04/15

Registrant information

Name

Siamak Yaghuobi

Name of organization / entity

Qazvin University of Medical Sciences & Health Services

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Qazvin University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Precoetaneous dilatation tracheotomy usage without fiber optic bronchoscope guidance on the patients candidate for tracheostomy and admitted to the intensive care unit on reduction of postoperative complications

Public title

Opening the airway of neck without the use of fiber-optic bronchoscope on reduction of postoperative complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age \geq 18; the patients who were not separated from ventilator after 2 weeks. Exclusion criteria: Patients with great thyroid; Patients with undesirable anatomy (Patients with short neck and the unknown landmark); Patients with Placket disorder and disturbance in the coagulation factors; patients with BMI \geq 30; patients needed to the emergent airway; Patients with fracture larynx; neck pieces instability; infection site of surgery.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd., Qazvin

City

Qazin

Postal code

Approval date

2017-05-27, 1396/03/06

Ethics committee reference number

IR. QUMS.REC.1396.140

Health conditions studied

1

Description of health condition studied

Respiratory failure or disorder

ICD-10 code

J96.9

ICD-10 code description

Respiratory failure, unspecified

Primary outcomes

1

Description

Tear of endotracheal tube cuff

Timepoint

Up to 24 hours after tracheostomy

Method of measurement

observation

2

Description

Pneumothorax

Timepoint

Up to 24 hours after tracheostomy

Method of measurement

Chest x-ray

3

Description

Subcutaneous emphysema

Timepoint

Up to 24 hours after tracheostomy

Method of measurement

Touching crepitus in the subcutaneous tissue

4

Description

Bleeding

Timepoint

Up to 24 hours after tracheostomy

Method of measurement

observation

5

Description

Extubation

Timepoint

Up to 24 hours after tracheostomy

Method of measurement

observation

6

Description

Incorrect placement of a tracheostomy tube

Timepoint

Up to 24 hours after tracheostomy

Method of measurement

observation

7

Description

Hypoxia and reduce saturation O2

Timepoint

Up to 24 hours after tracheostomy

Method of measurement

Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description

Entry tracheostomy tube without fiber optics

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei hospital

Full name of responsible person

Dr.Sareh Abdollahi

Street address

Padegan street, Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Reseach, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peymani

Street address

Shahid Bahonar Blvd., Qazvin

City

Qazvin

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice chancellor of Reseach, Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Sareh Abdollahi

Position

Resident of anesthesiology

Other areas of specialty/work

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Fax**Email**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty